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POSTSCRIPTS

AIMS AND SCOPE

Postscripts is the newsmagazine of the American Medical Writers Association Pacific-Southwest (AMWA Pac-SW) chapter. It publishes news, notices and authoritative articles of interest in all areas of medical and scientific writing and communications. The scope covers clinical/regulatory writing, scientific writing, publication planning, social media, current regulations, ethical issues, and good writing techniques.

MISSION STATEMENT

The mission of Postscripts is to facilitate the professional development of medical writers and serve as a tool to advance networking and mentoring opportunities among all members. Towards this mission, Postscripts publishes significant advances in issues, regulations and practice of medical writing and communications; skills and language; summaries and reports of meetings and symposia; book and journal summaries. Additionally, to promote career and networking needs of members, Postscripts includes news and event notices covering Chapter activities.

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INSTRUCTION FOR CONTRIBUTORS

We welcome contributions from members and non-members alike. Please contact editor.

ADVERTISING

Articles describing products and services relevant to medical writers may be considered or solicited. Members may submit advertisements for their services or products for free. Please contact editor for details.

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COVER: "Circle of Peace" by Gary Price at Saint Mary's Basilica grounds, Phoenix, Arizona / Picture by ajay malik

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IMPORTANT DATES

April 28 – May 1, 2013. AMWA Pacific Coast Conference, Asilomar, CA May 18, 2013. Women In Science and Technology (WIST) Conference, San Diego November 6-9, 2013. AMWA Annual Conference. Columbus, OH

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Greetings AMWA friends and colleagues,

AMWA Pacific Southwest's March madness gave great game in Thousand Oaks, with a winning medical writer outreach hosted by Amgen on March 16. Attended by approximately 110 aspiring and established medical writers, this wonderfully orchestrated event offered a window into myriad aspects of our profession: publications, regulatory writing, grants, freelancing, and communications. How-to's that included breaking into medical writing, networking tips, developing writing experience and portfolios, achieving work-life balance (I need to retake that session!) and dispelling myths about medical writing were covered in an engaging and interactive fashion. THANK YOU to the fantastic team of Aaron Van Etten, Cliff Chunn, Karen Driver, Lori Gorton, Kerri Hebard-Massey, Sue Hudson, Jon Nilsen, Chip Stark, Jenilyn Virrey, and Michele Vivirito.

Kathy Boltz writes in this month's PostScript's of another winning event that took place in Arizona late February, and offers many useful clues to solving the mysteries of Medline. Thank you Kathy!

April will shower us with our wonderful Asilomar conference this April 28-May 1. Don't be caught in the rain! There's still time to register! With 4 great workshops, many informative open sessions, and don't forget those network fireside happy hours, you may not even notice the beautiful beach sunsets, the roaming deer, and the melodic woodpeckers tapping out a tune.

Wishing you all a very happy start to Spring.

Warmly,

Jenny

Jennifer Grodberg, PhD, RAC President, AMWA Pacific-Southwest Chapter

Taking the Mystery Out of MEDLINE

By Kathy Boltz, PhD

The Arizona AMWA group heard librarian Cindy Elliott, MS, and information services librarian Ahlam A. Saleh, MD, MLS, both of the Arizona Health Services Library at The University of Arizona in Tucson, AZ, speak about getting more out of MedLine and other National Library of Medicine online offerings on February 23rd, 2013. A key concept for using PubMed more effectively is to notice the links at the bottom of the PubMed home page and take time to explore them.

The librarians provided a tour of the newer and older features in Medline Plus, which offers trusted health information. They explained that tutorials on using PubMed are available and that a handy link to them can be found at the bottom left of the PubMed homepage. The NCBI Bookshelf is helpful source of medical books available to the public freely online. Reputable and nonpartial information on medical topics is available from PubMed Health, which may often be useful for medical writers seeking background knowledge on a topic. Specifics on drugs can be found at the Drug Information Portal.

Advanced searching techniques were discussed, such as establishing as account and saving searches. The librarians explained the use of clinical queries, which allow searches to be limited to specific clinical research areas.

New PubMed features are described here, and news from the Pacific Southwest Region of the National Network of Libraries of Medicine is also available. The National Institutes of Health (NIH) publishes monthly newsletters, and a blog is available to help users understand new resources in the National Center for Biological Information. News on NIH behavioral and social science is also available. Several resources for toxicology and laboratory safety were shared, including an announcement of new resources, links for toxicologists, and links for lab safety.

Another new feature is that keywords are now found at the end of abstracts when they are supplied by publishers. PubReader breaks an article into multiple columns and pages to improve readability and navigation, and it is available as a mobile reader app

for tablets and all major web browsers. A gallery of mobile apps and sites is also available.

Changes to MeSH for 2013 were discussed. These include new descriptors, changes in MeSH terms, and deleted MeSH terms.

The librarians also discussed some of the blogs that are available, including the NCBI Insights Blog, which aims to help readers understand how to better use NCBI resources.

After all the information from the librarians, our group walked across the University of Arizona campus to enjoy lunch together at Pasco Kitchen and Lounge.

LINKS

MedlinePlus - http://www.nlm.nih.gov/medlineplus/ **PubMed Tutorials -**

http://www.nlm.nih.gov/bsd/disted/pubmedtutorial/ and http://www.nlm.nih.gov/bsd/disted/pubmed.html

NCBI Bookshelf - http://www.ncbi.nlm.nih.gov/books/

PubMed Health - http://www.ncbi.nlm.nih.gov/pubmedhealth/

Drug Information Portal -

http://druginfo.nlm.nih.gov/drugportal/drugportal.jsp

PubMed - http://www.ncbi.nlm.nih.gov/pubmed/

Establishing an account -

https://www.ncbi.nlm.nih.gov/account/register/?back_url=http://ww w.ncbi.nlm.nih.gov/pubmed/&partners-uri=cms:/account/partners

Clinical queries -

http://www.ncbi.nlm.nih.gov/pubmed/clinical

PubMed News -

http://www.ncbi.nlm.nih.gov/guide/howto/find-whats-new/

News Sources-Pacific Southwest Region - National Network of Libraries of Medicine - http://nnlm.gov/psr/newsbits/2013/01/

NIH Monthly News Letters - http://newsinhealth.nih.gov/ New National Center for Biological Information Blog-helps in understanding new resources

http://ncbiinsights.ncbi.nlm.nih.gov/

NIH Behavioral and Social Science News -

http://connector.obssr.od.nih.gov/

New Resources for Toxicology and Lab Safety -

http://nnlm.gov/psr/newsbits/2012/11/26/new-nlm-resourcesannounced-for-toxicology-and-laboratory-safety/ http://sis.nlm.nih.gov/enviro/especiallytoxicologists.html http://sis.nlm.nih.gov/enviro/labsafety.html

History and Search Bar Updates -

http://nnlm.gov/psr/newsbits/2013/01/31/pubmed-history-andsearch-bar-updates-2/

A "Download History" link will be added to the PubMed, MeSH and NLM Catalog Advanced page History feature. Using this link will generate History entries in the file "history.csv."

Mobile Access - Gallery of Mobile Apps and Sites

http://www.nlm.nih.gov/mobile/index.html

New MeSH 2013 - http://www.nlm.nih.gov/mesh/introduction.html New Descriptors - http://www.nlm.nih.gov/mesh/newd.html Changed - http://www.nlm.nih.gov/mesh/prefterm change.html Deleted - http://www.nlm.nih.gov/mesh/deleted.html

PubReader - http://www.ncbi.nlm.nih.gov/pmc/about/pubreader/

ACKNOWLEDGEMENT

Mary Stein deserves a thank you for sharing her helpful notes! Thanks, Mary!

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Attendees and librarian speakers at the February 2013 AZ AMWA meeting in the Computer Lab of the University of Arizona Library

What's Up(!) . . . at FDA and EMA

FDA updates By: Sally Altman and Kelly Dolezal

Several new drugs for the treatment of certain types of cancers or tumors met the FDA's regulatory standards for approval, as did a new drug for dyspareunia. The agency also approved a new radioactive diagnostic agent and a new contrast agent for magnetic resonance imaging. An FDA Drug Safety Communication warned of potentially fatal risks for some patients who take Zithromax (zithromycin), and the FDA's Office of Prescription Drug Promotion issued warnings to two drug makers for misleading or incomplete claims. The death of a pediatric study subject resulted in a clinical hold, and two drug makers issued voluntary recalls.

Selected	rda announcements	
03/12/13	The FDA issued a Drug Safety Communication concerning Zithromax or Zmax (zithromycin) and the risk of potentially fatal irregular heart rhythms. The agency warned that patients with known risk factors including QT interval prolongation, low blood levels of potassium or magnesium, a slower than normal heart rate, or use of certain drugs used to treat abnormal heart rhythms may increase the risk. Package inserts for the drug have been updated to include enhanced warnings about the risk of QT interval prolongation and torsades de pointes. ¹	
03/04/13	The FDA's Office of Prescription Drug Promotion issued a warning to ParaPRO, LLC for its drug Natroba (spinosad) stating that a video news release about the drug made efficacy claims, but failed to mention any risks, included a claim of superiority which was not substantiated, and failed to convey the drug's full indication. ²	
03/04/13	The FDA's Office of Prescription Drug Promotion issued a warning to Photocure USA for its drug Cysview (hexaminolevulinate hydrochloride) stating that labeling understated Cysview's risks by failing to characterize risks as contraindications, thereby creating the impression that the drug is safer than it actually is. ³	
O2/26/13 The FDA issued a Drug Safety Communication announcing that it had placed a clinical hole pediatric clinical studies of Sensipar (cinacalcet hydrochloride) following the death of a 14-y subject. The FDA continues to gather information on the death. Amgen suspended clinical death. Sensipar is used to decrease the release of parathyroid hormone. ⁴		
02/2 <mark>5/1</mark> 3	Olaax Corp nationwide voluntarily recalled a dietary supplement sold under the brand name MAXILOS WEIGHT ADVANCED softgels because they were found to contain undeclared Sibutramine. ⁵	
02/23/13	Affymax, Inc. and Takeda Pharmaceutical Company Limited voluntarily recalled all lots of Omontys (peginesatide) injection following postmarketing reports of serious life-threatening or fatal hypersensitivity reactions, including anaphylaxis. ⁶	

Selected FDA Approvals

Drug	Indication	Company		
Kadcyla	HER-2 antibody and microtubule inhibitor for the treatment of HER2-positive metastatic breast cancer in patients previously treated with trastuzumab and/or taxane ⁷	Genentech		
Stivarga	Kinase inhibitor for the treatment of metastatic colon cancer or locally advanced, unresectable, or metastatic gastrointestinal stromal tumor ⁷			
Osphena	Estrogen agonist/antagonist for the treatment of dyspareunia due to menopause ⁷	Shionogi		
Lymphoseek	Radioactive diagnostic agent for lymphatic mapping while draining a primary breast cancer or melanoma tumor site ⁷	Navidea		
Dotarem	Gadolinium-based contrast agent for magnetic resonance imaging of the brain, spine, and associated tissues ⁸	Guerbet		

What's Up(!) . . . at FDA and EMA

EMA Updates By: Wim D'Haeze

EUROPEAN MEDICINES AGENCY (EMA) ALERTS (21 FEB 2013 THROUGH 23 MAR 2013)

The alerts listed below cover the period from February 21, 2013 through March 23, 2013. Only key alerts thought to be of interest to the AMWA community were included; for additional updates and details refer to What's New on the EMA website.

GUIDELINES

- Draft guidance on the pharmacokinetic and clinical evaluation of modified-release dosages forms (open for publication consultation)a
- European Medicines Agency pre-authorisation procedural advice for users of the centralized procedure^b
- European Medicines Agency post-authorisation procedural advice for users of the centralized procedure^c

REPORTS/PAPERS

• Concept paper on the need to revise the guideline on the clinical development of fixed-dose combinations of medicinal products regarding dossier content requirements (open for public consultation)d

APPROVALS/REFUSALS

Compound	Indication/Use	Applicant	Advice [Note]
Defitelioe	Treat and prevent hepatic veno-occlusive disease in patients undergoing blood stem cell transplantation	Gentium S.p.A.	Negative opinion
HyQvia ^f	Replacement therapy in adults (18 years or Baxter Innovations GmbH Positive op over) with primary immunodeficiency syndromes		l Positive opinion
Stribild ^g	HIV-1 infection in adults aged 18 years and over who are antiretroviral treatment-naive or are infected with HIV-1 without known mutations associated with resistance to any of the three antiretroviral agents in Stibild	Gilead Science International Ltd.	Positive opinion
Aubagio ^h	Treatment of adult patients with relapsing remitting multiple sclerosis	Sanofi-Aventis Groupe	Positive opinion
Tecfidera ⁱ	Leber's hereditary optic neuropathy (LHON)	Biogen Idec Ltd.	Positive opinion
Stayveer ^j	Pulmonary arterial hypertension	Marklas Nederland BV	Positive opinion
Memantine ratiopharm ^k	Moderate to severe Alzheimer disease	Ratiopharm GmbH	Positive opinion
Labazenit ^I LTreatment of asthma in adults for whom a combination product containing an inhaled corticosteroid and long-acting beta-2 agoni required		Laboratoires SMB s.a.	Negative opinion

(continued from page 43). . . EMA Updates

Note: "positive" or "negative" opinion indicates the Committee for Medicinal Products for Human Use (CHMP) adopted a positive or negative opinion in regards of granting the marketing authorization, respectively, awaiting a final decision of the European Commission (EC).

GENERAL ANNOUNCEMENTS

- The European Medicines Agency released its 2013 work programme that focuses on increased efficiency and transparancy.m
- Adjusted fees for applications to the European Medicines Agency come into effect on April 1, 2013.

LINKS

EMA Website - What's New:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/landing/whats_new.jsp&mid =WC0b01ac058004d5c4 [Link]

a.

http://www.ema.europa.eu/ema/doc index.jsp?curl=pages/includes/document/document detail.jsp?webConte ntId=WC500140482&murl=menus/document library/document library.jsp&mid=0b01ac058009a3dc [Link] b.

http://www.ema.europa.eu/ema/pages/includes/document/open document.jsp?webContentId=WC500004069 [Link]

C.

http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500003981 [Link]

d.

http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webConte ntId=WC500139482&murl=menus/document library/document library.jsp&mid=0b01ac058009a3dc [Link]

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002393/smops/Negative/hu man smop 000491.jsp&mid=WC0b01ac058001d127 [Link]

f. http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002491/smops/Positive/hu man smop 000497.jsp&mid=WC0b01ac058001d127 [Link]

g.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002574/smops/Positive/hu man smop 000488.jsp&mid=WC0b01ac058001d127 [Link]

h.

i.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002514/smops/Positive/hu man smop 000496.jsp&mid=WC0b01ac058001d127 [Link]

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002601/smops/Positive/hu man smop 000498.jsp&mid=WC0b01ac058001d127 [Link]

j. http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002644/smops/Positive/hu man smop 000495.jsp&mid=WC0b01ac058001d127 [Link]

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002671/smops/Positive/hu man smop 000486.jsp&mid=WC0b01ac058001d127 [Link]

١.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002201/smops/Negative/h uman smop 000490.jsp&mid=WC0b01ac058001d127 [Link]

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news and events/news/2013/03/news detail 001735.j sp&mid=WC0b01ac058004d5c1 [Link]

n.

m.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news and events/news/2013/02/news detail 001725.j sp&mid=WC0b01ac058004d5c1 [Link]

(continued from page 42) . . . FDA Updates

For additional information, including full listings of biologic license application approvals, abbreviated new drug application approvals, applications for generic drugs and supplements to new drug applications or biologic license applications, see:

http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Reports.ReportsMenu. [Link]

http://www.fda.gov/Drugs/DrugSafety/ucm341822.htm?source=govdelivery [Link]

²http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFD A/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM341633.pdf [Link]

3http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFD A/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM343570.pdf [Link]

4http://www.fda.gov/Drugs/DrugSafety/ucm340551.htm [Link]

5http://www.fda.gov/Safety/Recalls/ucm340921.htm?source=govdelivery [Link]

6http://www.fda.gov/Safety/Recalls/ucm340893.htm?source=govdelivery [Link]

http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Reports.ReportsMenu [Link]

http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm344758.htm [Link]

"If I'm honest I have to tell you I still read fairy-tales and I like them best of all." - Audrey Hepburn

AMA-zing Style — the AMA Manual of Style Column

By Dikran Toroser, PhD, Amgen Inc.

Commonly Misused Terms in Medical Writing—Correct and Preferred Usage

We not infrequently are compelled to refuse publication to an article which contains valuable facts, but which is weighed down with so many imperfections as to discourage one—as does the porcupine—from closer investigation. JAMA (1904)1

The above quote, from a 1904 editorial in JAMA, may continue to hold true today. Although editors do consider manuscripts that are poorly written but are of good science, they may feel less confident about the data if the manuscript also contains imprecise wording. The AMA manual of style is a great resource for present day conventions that dictate the best term for a particular medical circumstance. In addition, many companies, including my own, have also developed their own style guides and can also be useful in this respect.

Correct and Preferred Usage of Some Common Medical Words and Phrases

abnormal, normal; negative, positive:

Examinations and laboratory tests and studies are not in themselves abnormal, normal, negative, or positive. These adjectives apply to observations, results, or findings.

Incorrect: The throat culture was negative. Correct: The throat culture was negative for β-hemolytic streptococci.

adverse effect, adverse event, adverse reaction, side effect: Side effect is a secondary consequence of therapy (usually drug based) that is implemented to correct a medical condition. The term is often used incorrectly when adverse effect, adverse event, or adverse reaction is intended. Since a side effect can be either beneficial or harmful, specific terminology should be used.

affect, effect: Affect (a-'fekt), as a verb, means to have an influence on. Effect (i-'fekt) as a verb, means to bring about or to cause. The 2 words cannot be used interchangeably.

association, relationship: Association is a connection between two variables in which one does not necessarily cause the other. Relationship implies cause and effect.

compose, comprise: Although these 2 verbs are often used interchangeably, compose is not synonymous with comprise.

Comprise means to be composed of or to include (the pituitary gland comprises the adenohypophysis and the neurohypophysis).

Compose means to make up or to be a constituent of (the adenohypophysis and the neurohypophysis compose the pituitary gland). The phrase comprised of is never correct.

die from, die of: Persons die of, not from, specific diseases or disorders.

fewer, less: Fewer and less are not interchangeable. Use fewer for number (individual persons or things) and less for volume or mass (indicating degree or value).

follow, follow up, observe: Cases are followed. Patients are not followed but observed. However, either cases or patients may be followed up (eg. the maintenance of contact with or reexamination of a person or patient, especially after treatment). Their clinical course may be followed.

gender, sex: Sex is defined as the classification of living things as male or female according to their reproductive organs and functions assigned by chromosomal complement. Gender refers to a

person's self-representation as a man or a woman, or how that person is responded to by social institutions on the basis of the person's gender presentation. Gender is rooted in biology and shaped by environment and experience. In most instances, authors of articles in biomedical publications intend the word sex.

operation, surgical procedure, surgeries,

surgery: Surgery can mean surgical care, surgical treatment, or surgical therapy (ie, the care provided by a surgeon with the help of nurses and other personnel from the first consultation and examination, through the hospital stay, operation, and postoperative care, until the last follow-up visit is complete).

An operation is what occurs between the induction of and the patient's emergence from anesthesia—incision, dissection, excision, and closure—the surgical procedure.

Surgery is what a surgeon practices or a particular medical specialty. An operation is what a surgeon performs. In this context, there is no such word as surgeries. As those of us from the United Kingdom know, physicians' or dentists' offices are also known as surgeries.

preventative, **preventive**: As adjectives, preventive and its derivative preventative are equal in meaning. JAMA and the Archives Journals prefer preventive.

respective, respectively: This one is a favorite for medical writers that are often presenting lists embedded in text. In essence, the words indicate a one-to-one correspondence that may not otherwise be obvious between members of 2 series. When only 1 series, or none at all, is listed, the distinction is meaningless and should not be used.

Incorrect: The 2 patients are 12 and 14 years old, respectively.

Correct: Kate and Jake are 12 and 14 years old, respectively.

survivor, victim: In scientific publications, use of the word victim—when describing persons who survive physical, domestic, sexual, or psychological violence or a natural disaster—should be avoided. Similarly, avoid labeling (and thus equating) people with a disability or disease as victims (eg, AIDS victims or stroke victim).

Victim may imply a state of helplessness. It perpetuates the stereotype of a passive person who cannot recover from the effects of the malady. Survivor may be more appropriate (eg, rape survivor, tsunami survivor). However, if a person who experienced a trauma has died, as the use of victim may be appropriate (victim of a land mine explosion).

ultrasonography, **ultrasound**: These terms are not interchangeable. When referring to the imaging procedure, use ultrasonography. Ultrasound refers to the actual sound waves themselves during ultrasonography.

Further details can be found on pages 381-404 of the AMA Manual of Style 10th edition.

REFERENCES

1. Why are scientists poor writers [Queries and Minor Notes]? JAMA. 1904; 42(7):477.

"Why change? Everyone has his own style. When you have found it, you should stick to it." - Audrey Hepburn

de-MS-tifying Word

By Susan Chang

Reprinted from: Postscripts. 2012 Sept;2(7):6.

In this month's installment, we'll explore some useful automated features in MS Word 2007. These features will save you time and increase the quality of your documents!

THERE'S SAFETY IN NUMBERS

Instead of manually numbering tables and figures in a document, try "captioning" their titles. Captioning automatically numbers tables and figures sequentially and allows you to generate and quickly update hyperlinked cross-references and Table of Contents (TOCs).

TIP: An easy way to update everything is to select the entire document (Ctrl+A), then hit F9.

To insert a table (or figure) title caption: Place your cursor where the table (or figure) title should be located. Go to References tab → Captions group → Insert Caption → Select Table (or Figure) from the pull-down menu → Adjust the numbering format as needed → Type in the title of the table (or figure) → Click OK. The table (or figure) is now captioned!

CROSS THAT REFERENCE WHEN YOU COME TO IT

To electronically link in-text references to tables and figures, the captioned title must be cross-referenced. Directions for cross-referencing section headings are also included below.

To cross-reference a table, figure, or section: Begin by placing your cursor where the cross-reference should be. Go to Insert tab → Links group → Cross-reference tab → Follow the instructions in Table 1 for the type of cross-reference you need.

Table 1. Cross-Reference Options

File Edit View

Object to hyperlink	Under "Reference type," Select:	Under "For which (caption)," Choose:	Under "Insert reference to," Select:
Figure	Figure	Figure of interest	Only label and number
Table	Table	Table of interest	Only label and number
Section*	Heading	Costion title of interest	Heading Number
	Numbered item**	Section title of interest	Paragraph Number

Word woes? Email me at SKC@SusanChangConsulting.com with your MS Word questions! ©2012 Susan Chang. All rights reserved.

Sneak Peak into the Latest AMWA Journal

By Victoria A. Love, PhD

AMWA Journal Vol 27 No 4 2012: Preview of Feature Articles

Clarifying Solutions

The path to investigational new drug (IND) submission imposes considerable demands on resources. Katz (p. 158) explains that the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) was formed to facilitate the development of medicines and that the ICH created E3 guidelines that were adopted by the European Union, Japan, and the United States. Standardizing the format of clinical study reports (CSR) enabled submission of the CSR to each of the three ICH regions. Additionally, implementation of the Common Technical Document (CTD) consolidated all information related to an IND application. While these measures simplified submissions, individual interpretation of the E3 guidelines and instructions for completing the CSR and CTD caused notorious delays and disagreements. Katz describes that the Drug Information Association identified discrepancies and recommended clarifying instructions that were supported by the US Food and Drug Administration (FDA). In June 2012, the ICH approved a Q&A document to the E3.

Balancing Act

For many professionals, obtaining work-home balance is a worthy pursuit. In the Freelance Forum (p. 164), well-established medical writers candidly discuss juggling businesses with the rest of their lives. Each interviewee admitted to either having "crazy hours"—that is, working greater than 10 hours daily, frequently working weekends—or both. How do these driven entrepreneurs make down time? Among other things, Elizabeth Smith and her business partner look forward to a long weekend once per quarter and are active with church and volunteerism. Brian Bass exercises faithfully each morning and savors hard-earned vacations. Cathryn Evans occasionally works 12-15 hour days for 3-week stretchers. To manage, she plans vacations with non-refundable deposits because she is less likely to cancel, works out, and finds time for friends. Lori De Milto struggles to identify free time, but takes an entire weekend day off once per month, enjoys yoga and appreciates time away from her desk while running errands or spending time with family. Learning to say "no" on occasion, or passing on assignments if necessary are other management strategies mentioned.

Upside of Down

During the best economic times, shifting into a new career may pose challenges; however, such daring professional feats are possible—even in a down market. In CME Rising, Johanna Lackner Marx (p. 166) writes that tele-internships in CME are an emerging alternative to traditional modes of career training. While returning to academic institutions, completing e-learning modules and participating in educational programs offered by professional organizations are valuable sources for career development, tele-internships are uniquely designed to provide trainees with on-the-job experience that will be attractive to companies that hire CME writers. To make the best of spare time between jobs or paid assignments, the author makes suggestions about choosing a mentor and describes the characteristics of a productive tele-internship.



AMWA Pacific Coast Conference

(April 28 – May 1, 2013) Asilomar Conference Grounds 800 Asilomar Blvd Pacific Grove. California 93950 www.visitasilomar.com

Medical Communications: Expand Your Reach and Focus Your Skills

Join us for 3 days of small-group workshops, fireside forums, and provocative conversations with writers, editors, scientists, and other medical communicators in the beautiful, relaxing retreat setting of the Asilomar Conference Grounds. Here's just a taste of the forums.

- Regulatory documents for the non-regulatory writer
- Conducting successful document review meetings
- Technical tricks for efficient reviews and revisions.
- Good publication practices
- Medical communications careers (panel discussion) ...and more!

Keynote Session: Globalization's Impact upon Health in the Developing World, by Michele Barry, M.D., F.A.C.P; Senior Associate Dean for Global Health/Director Global Health Initiatives, Stanford University

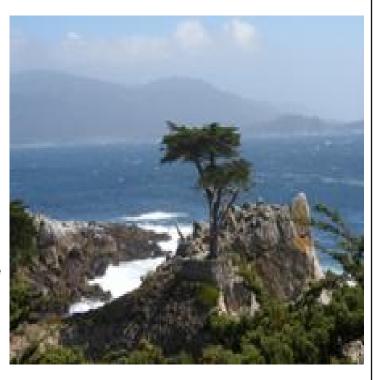
Take advantage of this rare opportunity to take an Advanced workshop at a Chapter conference.

Workshops

- Essential Ethics for Medical Communicators (ES) [2006], Cindy Hamilton
- Business Aspects of a Freelance Career (B/FL) [2500], Cindy Hamilton
- Summarizing Clinical Efficacy Data for a New Drug Application (RR) [4013], Peggy Boe
- Reporting Randomized Trials in Science Journals (ADV) [719], Tom Lang

Additional conference information available online at

http://www.amwapacsw.org/events/PCC 2013/index.html



Answering Difficult Interview Questions

By Irene Yau, PhD, Allergan Inc.

This month's career column will be focused on preparing and answering a couple of difficult interview questions.

• Interview Question 1: Tell me about your weaknesses.

Let's think about why hiring managers would ask this question. One reason is to see if there are any red flags that the candidate will disclose. Another reason hiring managers like to ask this question is to see how the candidate articulates an uncomfortable question. It's no secret that no employee is perfect. But it is important to have employees who are willing to work on improving their flaws and learn from their weaknesses.

Answer this question in a way to turn your weakness into a strength or talk about how you overcome your weakness. Don't use a weakness that would signal the hiring manager to believe you wouldn't be able to do the job (saying that your weakness is composing coherent sentences for a writing job won't get you very far). Stick to work-related weaknesses and leave personal weaknesses out. Avoid the cliché weaknesses like "I work too hard" or "I am a perfectionist".

Examples:

"I have a tendency to say yes and get overcommitted," Nicole Williams (LinkedIn career expert) suggests. "Then follow that with an example of how you are working on prioritizing and setting personal limits."

"I am extremely impatient. I expect my employees to prove themselves on the very first assignment. If they fail, my tendency is to stop delegating to them and start doing everything myself.

To compensate for my own weakness, however, I have started to really prep my people on exactly what will be expected of them."

Interview Question 2: What salary do you want?

Let's think about why this question would be asked during an interview. The company wants to make sure that your salary expectations fall within the price range for what the position has been budgeted for.

Research the salary range for your prospective position beforehand from places such as glassdoor.com or salary.com. Try not to answer this question directly. Talk about how you believe this company is reputable and will compensate their employees fairly. If they persist, give a salary range rather than a specific number. In turn, you can also ask (respectfully, of course) what the salary range for this position is or what the position has been budgeted for. You can let them know you are flexible with the salary range if this is the case.

Remember that external recruiters are paid based on a percentage of your salary so they will want to make sure you are fairly compensated.

Examples:

"I am sure we will be able to come to a fair agreement if the position represents a good fit for us both." Alternatively, you can state that your required salary depends upon the duties and responsibilities of the role; you will be happy to provide full disclosure once you are further along in the process.

"If I am your candidate of choice and, in turn, if this is the right opportunity for me, then I know the offer will be more than fair."

Do not respond with "I just need a job, anything is fine"

References:

- 1) 301 Smart answers to tough interview questions Vicki Oliver http://www.businessinsider.com/29-smart-answers-to-tough-interview-questions-2012-5?op=1#ixzz2Nm7W8n9Q [Link]
- 2) http://money.usnews.com/money/blogs/outside-voices-careers/2013/02/20/master-the-5-toughest-interviewquestions [Link]
- 3) http://www.forbes.com/sites/jacquelynsmith/2013/02/19/how-to-talk-about-your-biggest-weakness-in-a-jobinterview/ [Link]
- 4) http://www.flexjobs.com/blog/post/how-to-answer-salary-interview-questions-glassdoor/ [Link]
- 5) http://www.aarp.org/work/job-hunting/info-07-2008/10 tough interview questions.2.html [Link]
- 6) http://www.forbes.com/sites/jacquelynsmith/2013/01/11/how-to-ace-the-50-most-common-interviewquestions/3/ [Link]
- 7) http://jobs.aol.com/articles/2011/10/31/how-to-answer-the-dreaded-salary-question/ [Link]

"Nothing is impossible, the word itself says 'I'm possible'!"
—Audrey Hepburn

Looking for new opportunities in technology? Looking for networking opportunities with science and technology leaders? Looking to enhance your professional skills and find balance between your professional and personal lives?

We invite you to attend the

Women In Science and Technology (WIST) Conference Saturday, May 18, 2013 8 AM to 5 PM

At The Faculty Club on the campus of UC San Diego Advanced Registration Required at www.wist2013.org Deadline: May 14 (Discount for registration by April 20)

Keynote speakers:

Jeanne Ferrante, Associate Vice Chancellor for Faculty Equity, Associate Dean of the Jacobs School of Engineering, and Professor of Computer Science and Engineering, UC San Diego

Barbara Bry, Chief Operating Officer, Blackbird Ventures

Who Should Attend?

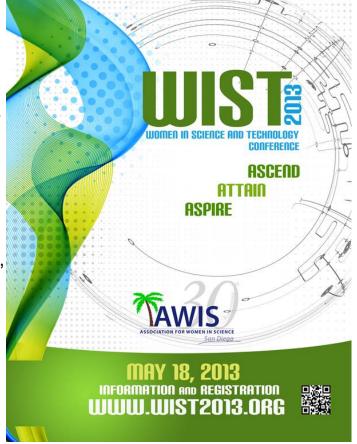
Individuals at all levels in Science, Technology, Engineering, and Mathematics (STEM) fields.

What is the WIST conference about?

A one day symposium focusing on career and personal development, networking, an inspiring prominent keynote speakers. Exciting and informative workshops and seminars are available for individuals at all stages of their careers in both academia and industry. An excellent opportunity to network, develop new skills, and explore career opportunities with 300 attendees from the scientific community.

What is the Purpose of the WIST conference?

To empower women in STEM fields at all levels to enhance their careers through networking, discussion of relevant career development topics, and exposure to a wide range of specialties in STEM fields



wide range of specialties in STEM fields. Now is the opportunity to make positive changes in our careers and lives!

For more information and registration, please visit our website at: www.wist2013.org

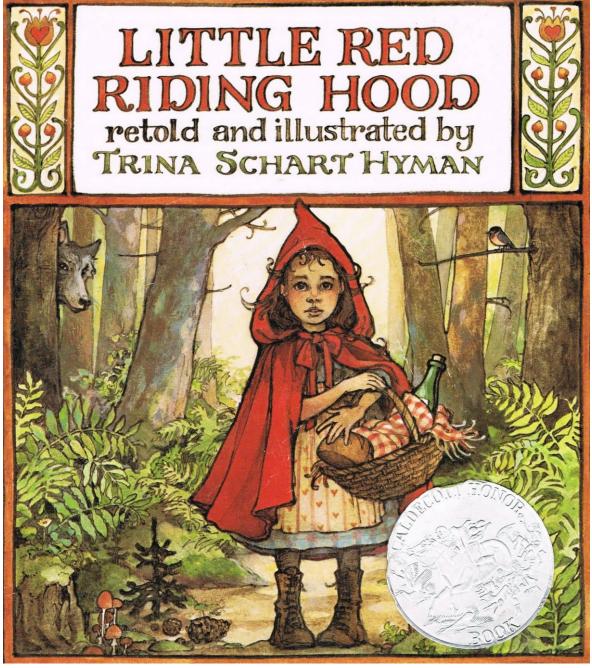
- "Auntie Mame, who was the british lady?"
- 'Oh, she's from Pittsburgh'
- 'But she had the acc-'
- 'Well, when you're from Pittsburgh you gotta do something"
- Audrey Mepburn

Pittsburg is only three hours from Columbus



http://www.amwa.org/default.asp?id=575

Little Red Riding Hood



Little Red Riding Hood. Retold and illustrated by Trina Schart Hyman, 1983.

April is the anniversary of New Hamshire-based illustrator of children's books, Trina Schart Hyman (April 8, 1939 - November 19, 2004). A three time winner of Caldecott Medal, the highest honor in her field, she illustrated over 150 children's books and retold several classics during her lifetime. April is also the month to pick up children's book and influence young minds—April 10th is Encourage a Young Writer Day. International Children's Book Day is on April 2nd, and this month we also celebrate another great story teller, author Hans Christian Andersen (born, April 2, 1805).

Trina's obit in New York Times: http://www.nytimes.com/2004/11/24/books/24hyman.html

—Editor